

## Be prepared for 2013: obligations and recommendations to the registrants

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## **Why registrants should seriously prepare for the 2013 registration deadline?**

- More substances are expected to be registered, more specialty chemicals, probably lower number of registrations per substance.
- More difficult SIEFs management: less members, less resources and knowledge, smaller companies, more SIEFs run by just the Lead Registrant (LR) and less experienced LR's.
- Fewer substances will be covered by consortia.
- No more HPV bulk chemicals/substances.
- Need to understand the impact on your costs and margins: your 2012 budgets may need to allocate expenditures to achieve 2013 compliance.
- Supply Chain partners will soon want to understand your level of preparedness.
- Less data available. More Annex IX test proposals. Limited laboratory capacity to run specific tests. Scientific support for alternative test methods required.
- Limited number of experienced consultants available.

## **Timing for an optimal situation:**

- Summer 2011 onwards: Start SIEF work
- September 2011 onwards: Ensure that staff is trained and competent to complete REACH 2013 registration. If required choose a consultant to support your registration processes.
- June-December 2011: Substance ID, data sharing, hazard data
- 2012: Chemical assessment
- January-March 2013: Lead is registering
- April-June 2013: Members are registering

## **Obligations and recommendations as a registrant for 2013:**

**Joint submission is a joint effort; therefore all SIEF members are responsible for the registration and they need to be active.**

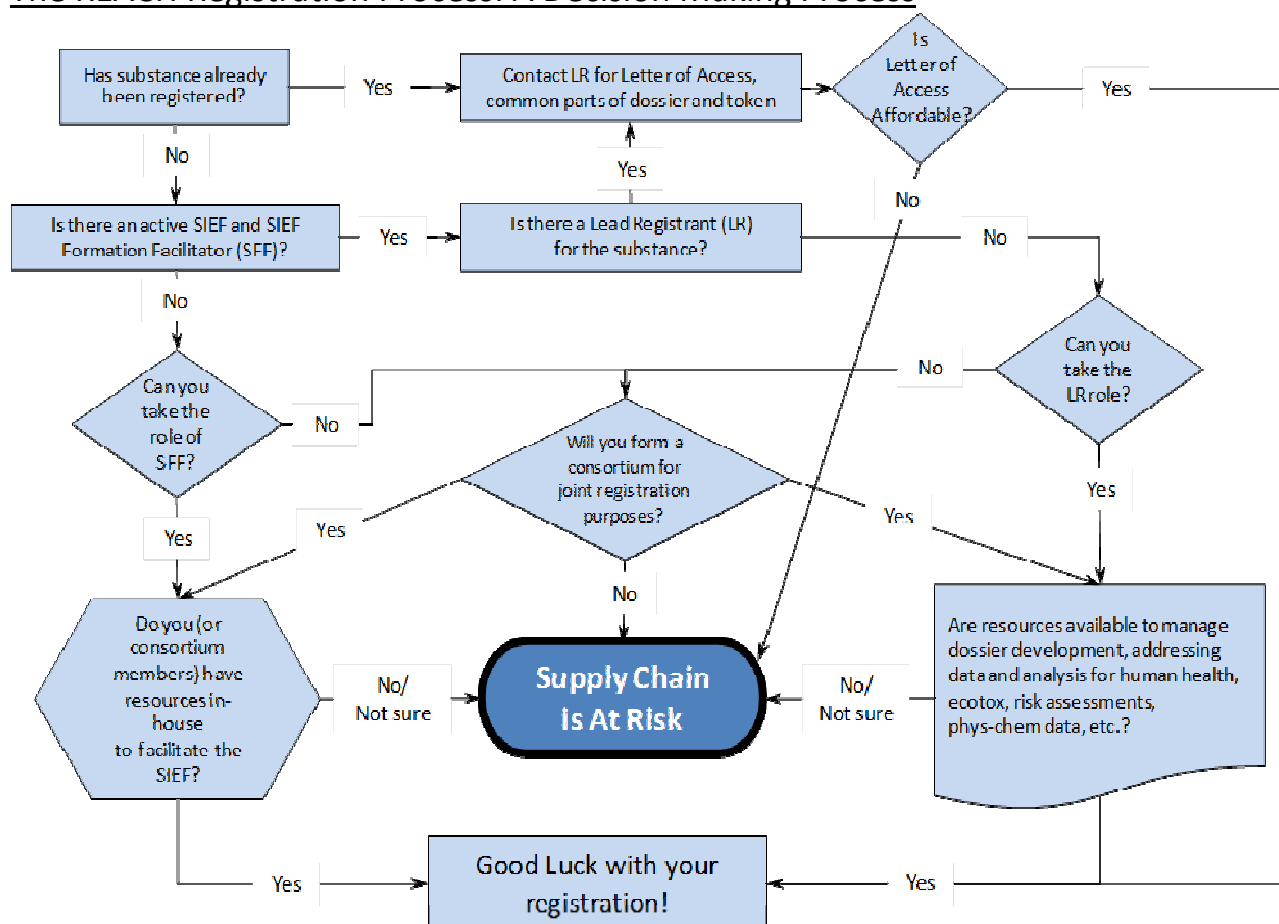
## **Check whether a SIEF is already working. Has the substance already been registered in 2010?**

- **If yes,**
  - Inform the Lead Registrant of 2010 of your intention to register in 2013. LRs remain Lead of the joint submission until at least 1 June 2018. Usually they shall inform (pre-) SIEF members of their existence.
  - Then consider substance identity and verify whether you have the "same" substance.
  - Start data sharing negotiations: newcomers in the SIEF, namely registrants for 2013, are only required to share costs of data needed for their tonnage band: Annex X not required.
  - LR shall ensure that data sharing conditions are not only fair, transparent and non-discriminatory but also proportionate to the information needs.
  - LR will need to distribute the REACH-IT tokens to new registrants. If the LR did not provide it, ask for your REACH-IT token to register as a member of the "joint submission".

- **If you don't know,**
  - Check the list of registered substances on the ECHA website: <http://apps.echa.europa.eu/registered/registered-sub.aspx#phasein> . If some substances are not on the list, it might be because the registrant has requested confidentiality on the name.
  - You should then verify within the SIEF or industry associations if the substance was registered in 2010.
    - Check pre-SIEF pages in REACH-IT, contact SIEF members or industry associations.
    - Ask ECHA Helpdesk to be put in contact with the Lead Registrant.
  - Service providers can help you to find out the activity related to your substance: Are there potential registrants for the substance? Is there an existing SIEF? An existing LR? Do the potential registrants wish to be active in the SIEF? To be passive?
- **If no,**
  - Some 2013 SIEFs already exist, the Lead may have already been nominated. You should have been informed by the SIEF Formation facilitator (SFF) in REACH-IT. Verify in REACH-IT, on the ECHA website or with industry associations whether a SFF exists for your substance.
  - If not, start the process of SIEF formation (see page 3)

**It is very important to note that a SFF has no legal status under REACH. In practice the nomination of a SFF does not always mean that they will start the registration process. Even if a SFF has been nominated in your SIEF, we advise to start the SIEF discussion and the appointment of a LR as soon as possible.**

### The REACH Registration Process: A Decision Making Process



## Recommendations to the co-registrants for 2013:

- Get to know your co-registrants and identify your Lead registrant.
- Familiarise yourself with tools and guidance available (IUCLID, REACH-IT, Chesar, Technical completeness check, Business rules, fee calculator & dissemination tools). Read the Data submission Manual 4; all Guidance can be found: [http://guidance.echa.europa.eu/guidance\\_en.htm](http://guidance.echa.europa.eu/guidance_en.htm)
- If you have multiple substances to register, prioritise one for early registration to gain hands-on experience on the registration process.
- **If applicable, warn your customers about potential consequences if you decide not to register a specific substance.**

## SIEF formation

### *By the end of 2011:*

- Contact pre-SIEF members to identify those registering in 2013 and appoint a SFF or by-pass the existing SFF in certain situations
- Verify substance sameness and form the SIEF
- Prepare SIEF agreement :  
[http://www.cefic.org/Documents/IndustrySupport/REACH\\_SIEF\\_Agreement\\_02.06.09\\_final.doc](http://www.cefic.org/Documents/IndustrySupport/REACH_SIEF_Agreement_02.06.09_final.doc)
- Nominate a Lead Registrant
- Collect data needed for Annexes VI to IX
- Agree who will perform the missing tests

### *At the latest by 30 May 2012:*

- Inform your downstream users: registrants should know by that time their DUs' uses

### *By end of 2012:*

- Prepare your Chemical Safety Assessment

## Recommendations to the Lead Registrant for 2013:

- Nominate yourselves to ECHA to benefit from special services, e.g. webinars and to create transparency <https://comments.echa.europa.eu/Comments/LeadRegistrantNomination.aspx>
- In case you want to start the SIEF work as soon as possible and you don't want to commit yourself to be the LR for the moment, you can act as a provisional LR. Your legal obligations will only start from the moment you are formally appointed by the SIEF members therefore you can nominate yourself to ECHA and start the work. When acting as a LR or a potential LR, you should document what you are doing e.g. keep record of the money and time you spend to work for the SIEF.
- Inform the affected supply chain that your SIEF is functioning and your substance will be registered.
- Make sure all SIEF members are aware of tools and guidance available (IUCLID, REACH-IT, Chesar, Business rules, Technical completeness check, fee calculator & dissemination tools). Make use of the experience gained in 2010. Read the Data submission Manual 4; all Guidance can be found: [http://guidance.echa.europa.eu/guidance\\_en.htm](http://guidance.echa.europa.eu/guidance_en.htm)
- Use preferably Chesar for your chemical safety assessment and your CSR.

## Communicate to the SIEF in time:

### *1st Email to entire pre-SIEF; timing May-June 2011:*

- Introduction of Candidate LR and launch of a LR vote
- Propose a substance identification profile (SIP):  
[http://www.cefic.org/Documents/IndustrySupport/SIP\\_template\\_final.xls](http://www.cefic.org/Documents/IndustrySupport/SIP_template_final.xls)
- Registration intent survey (SIEF codes):  
[http://www.cefic.org/Documents/IndustrySupport/Invitation\\_4\\_digits\\_0309.doc](http://www.cefic.org/Documents/IndustrySupport/Invitation_4_digits_0309.doc)
- Decide whether an intermediate/full dossier is required.
- Call for ALL available data; not just vertebrate animal data.

### *2nd Email to entire SIEF, timing Q2/2011*

- Inform that results of survey are posted on SIEF management tool website. Some commercial service providers have developed efficient IT tool.
- If applicable inform SIEF that progress can be checked on LR's web site (recommended).
- Confirmation of LR and notification to ECHA of the LR's identity.

### *3rd Email to entire SIEF*

- After hazard assessment:
  - Propose C&L by asking for agreement (no reaction means agreement)
  - Then post the agreed C&L on the LR website

### *4th Email to all Legal Entities' interested in 2013 registration; timing 2012*

- Cover letter to SIEF agreement
  - Explain cost structure: define the reimbursement system or a fixed price for Letter of Access. Include potential additional cost for work after registration e.g. executing test proposals, evaluation etc.
  - Information to be provided upon payment of the Letter of Access:
    - IUCLID export file.
    - Right to refer to a Joint submission.
    - Token.
    - Be clear on CSR: define whether they will be jointly prepared/submitted or not; that they are developed for most common uses etc.
    - More information on Letter of Access:  
[http://www.cefic.org/Documents/IndustrySupport/Cefic\\_recommendation\\_letter\\_of\\_access\\_FINAL.pdf](http://www.cefic.org/Documents/IndustrySupport/Cefic_recommendation_letter_of_access_FINAL.pdf)
    - [http://www.cefic.org/Documents/IndustrySupport/Cefic-overview-models%20LoA\\_02%2008%2010.doc](http://www.cefic.org/Documents/IndustrySupport/Cefic-overview-models%20LoA_02%2008%2010.doc)
- SIEF agreement
  - Which uses will be covered in the CSR.
  - Accepting means agreement with the substance identification profile.
  - More information on SIEF agreement:  
[http://www.cefic.org/Documents/IndustrySupport/REACH\\_SIEF\\_Agreement\\_02.06.09\\_final.doc](http://www.cefic.org/Documents/IndustrySupport/REACH_SIEF_Agreement_02.06.09_final.doc)

## **Do not forget to:**

### *Find an agreement on Cost sharing:*

- Key words are transparency and fairness in cost structure and content:
  - Explanation of cost sharing system e.g. cover letter.
  - Pay for the data you need (tonnage band, intermediate...)
- Administrative costs may include: SIEF management, preparation of IUCLID dossier, RSS, CSR, generation of invoices, letters of access, provision for reimbursement (with a threshold?) etc.
- More information on Cost sharing: [http://www.cefic.org/Documents/IndustrySupport/Cefic-note\\_fair-cost-sharing%20in%20SIEFs\\_070910.pdf](http://www.cefic.org/Documents/IndustrySupport/Cefic-note_fair-cost-sharing%20in%20SIEFs_070910.pdf) and [http://www.cefic.org/Documents/IndustrySupport/Cefic-note\\_fair-cost-sharing%20in%20SIEFs\\_070910.pdf](http://www.cefic.org/Documents/IndustrySupport/Cefic-note_fair-cost-sharing%20in%20SIEFs_070910.pdf)

### *Some communication rules:*

- Use older version of MS Office, or send document in pdf format.
- Make use of web based SIEF management tool.
- Download XML from ECHA pre-SIEF page file for EACH round of emails.
- Keep all undeliverable emails in file.
- **In general: No reaction means agreement with LR proposals!!!!!!**

## Glossary

C&L	Classification and labeling
Chesar	Chemical safety and report tool
CSR	Chemical Safety Report
DU	Downstream user
ECHA	European Chemicals Agency
LR	Lead Registrant
RSS	Robust Study summary
SIEF	Substance information exchange forum
SIP	Substance identification profile
Substance ID	Substance Identity